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4 ARAMIC LLC, et al.,
5 Plaintiffs,
6 v.
7 REVANCE THERAPEUTICS, INC., et al.,
8 Defendants.
9

10 Case No. [21-cv-09585-AMO](#)
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13 **ORDER GRANTING DEFENDANTS'**
14 **MOTION TO DISMISS**
15

16 Re: Dkt. No. 65
17

18 This is a securities fraud case about the U.S. Food and Drug Administration's review of a
19 drug developed by Revance Therapeutics, Inc. ("Revance"). Defendants' motion to dismiss was
20 heard before this Court on August 10, 2023. Having read the papers filed by the parties and
21 carefully considered their arguments therein and those made at the hearing, as well as the relevant
22 legal authority, the Court hereby **GRANTS** the motion to dismiss, for the following reasons.
23

24 **I. BACKGROUND¹**
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26 Plaintiffs Aramic LLC ("Aramic") and Tang Family Investor Group are stockholders of
27 Defendant Revance Therapeutics, Inc. ("Revance"), who seek to represent purchasers of Revance
28 stock between November 25, 2019, and October 11, 2021 (the "class period"). FAC ¶ 1. Revance
is a biotechnology company that develops and sells skin treatment drugs. FAC ¶ 2. During the
class period, Defendants made statements regarding the company's attempt to secure U.S. Food
and Drug Administration ("FDA") approval for their drug candidate DAXI. FAC ¶¶ 2-3, 7-8.
DAXI is a drug used to treat frown lines. FAC ¶ 2.

29
30 ¹ The Court accepts Plaintiffs' allegations in the complaint as true and construes the pleadings in
31 the light most favorable to Plaintiffs. See *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d
32 1025, 1031 (9th Cir. 2008) (citation omitted).

1 To obtain FDA approval, drug developers must submit to the FDA a Biologics License
2 Application (“BLA”), which provides testing results, product development information, and
3 descriptions of manufacturing processes. FAC ¶¶ 4, 53. As part of the BLA review process, the
4 FDA typically conducts an inspection to evaluate company compliance with Current Good
5 Manufacturing Practices (“cGMP”) regulations, assess readiness for commercial manufacturing,
6 ensure conformance to the submitted application, and ensure the integrity of data submitted with
7 the BLA. FAC ¶¶ 4, 49, 53. After the inspection, the FDA may issue a Form 483 with
8 observations of potential non-compliance with cGMP regulations. FAC ¶¶ 49, 52, 75-76. The
9 company then has fifteen days to respond. FAC ¶ 109. If the FDA does not approve a BLA, it
10 issues a Complete Response Letter (“CRL”) explaining why the FDA did not approve the drug.
11 FAC ¶¶ 21, 146.

12 On November 25, 2019, Revance announced its submission of a BLA for DAXI, which it
13 had been manufacturing since 2010, stating that it anticipated potential FDA product approval at
14 the end of 2020. FAC ¶ 6. Due to COVID-19, the FDA delayed its pre-approval inspection of the
15 manufacturing facility until July of 2021. FAC ¶ 15.

16 After completing the inspection on July 2, 2021, the FDA provided Revance with a Form
17 483, containing five “inspectional observations.” FAC ¶¶ 74, 77. The first two observations
18 focused on the deterioration of Revance’s working cell banks (“WCBs”), which are cell tissues
19 extracted from a repository to produce drug substance and product, and Revance’s new WCB not
20 being fully qualified and being a different manufacturing process than proposed in the BLA. FAC
21 ¶¶ 12, 78-81, 87-90. The third observation noted that Revance did not have a “quality agreement”
22 in place with a third-party facility. FAC ¶ 92. The fourth and fifth observations involved how
23 Revance calculated percentage yield and record-keeping details. FAC ¶¶ 97-104.

24 Revance provided a written response to the Form 483 in July 2021. FAC ¶ 110. It
25 explained that it had enough drug substance from a qualified WCB to support commercial
26 production of DAXI. FAC, Ex. C (ECF 58-3) (Form 483 Response) at 10. Revance also
27 explained that it planned to qualify the new WCB, and believed that qualification was a “post
28 approval activity.” *Id.* To that end, Revance stated that it “fully understands that the current WCB

1 aged and our new WCB will not be fully qualified at the licensure. However, we have a fully
2 functional [redacted] that can last for more than [redacted] as well as [drug substance] inventory to
3 support [drug product] production through [redacted]. Given that supply shortage is not a
4 concern, Revance proposes to submit a post approval application for the WCB qualification
5 package per approved protocol once available. . . [.]” *Id.* at 10-11. Revance also disagreed with
6 the FDA observation that it was using a different manufacturing process than that proposed for
7 licensure. *Id.* at 7.

8 To address the remaining observations, Revance executed a quality agreement with third-
9 party facility on July 16, 2021, adjusted the way it calculated percentage yield, and amended its
10 record-keeping details and photo clarity. Ex. C at 12-14, 17-18. On August 5, 2021, Revance
11 issued a press release stating that the FDA initiated its pre-approval inspection in June and that
12 Revance anticipated approval of DAXI in 2021. FAC ¶ 150. On October 15, 2021, the FDA
13 issued a Complete Response Letter (“CRL”) denying Revance’s BLA for DAXI. FAC ¶ 168. On
14 March 8, 2022, Revance resubmitted its BLA. FAC ¶ 175. In September 2022 after issuance of
15 another Form 483 in March 2022, the FDA approved DAXI. FAC ¶¶ 178-79.

16 On December 10, 2021, Plaintiffs filed the instant securities class action. ECF 1. On
17 November 7, 2022, Plaintiff filed the operative complaint, the First Amended Complaint (“FAC”)
18 against Defendants Mark Foley, Tobin Schilke, and Abhay Joshi (“Individual Defendants”) and
19 Revance (collectively, “Defendants”) alleging that Defendants made 29 false or misleading
20 statements about the timing and likelihood of FDA approval of DAXI in violation of Sections
21 10(b) and 20(a) of the Exchange Act in the following general categories:

- 22 (1) Defendants failed to disclose significant quality control and manufacturing
23 deficiencies that made FDA approval unlikely;
- 24 (2) Defendants’ statements about readiness for FDA inspection and confidence in
25 FDA approval were false and misleading given the deficiencies that existed; and
- 26 (3) Defendants continued statements expressing confidence in FDA approval after
27 the Form 483 was issued were false and misleading.

28 See FAC (ECF 58) ¶¶ 7, 269-84. On January 23, 2023, Defendants filed a motion to dismiss the

1 complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which
2 relief can be granted. Motion (ECF 65).

3 **II. LEGAL STANDARD**

4 Federal Rule of Civil Procedure 8(a) requires that a complaint contain “a short and plain
5 statement of the claim showing that the pleader is entitled to relief.” A defendant may move to
6 dismiss a complaint for failing to state a claim upon which relief can be granted under Federal
7 Rule of Civil Procedure 12(b)(6). “Dismissal under Rule 12(b)(6) is appropriate only where the
8 complaint lacks a cognizable legal theory or sufficient facts to support a cognizable legal theory.”
9 *Mendiondo v. Centinela Hosp. Med. Ctr.*, 521 F.3d 1097, 1104 (9th Cir. 2008). To survive a Rule
10 12(b)(6) motion, a plaintiff must plead “enough facts to state a claim to relief that is plausible on
11 its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is facially plausible
12 when a plaintiff pleads “factual content that allows the court to draw the reasonable inference that
13 the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

14 In reviewing the plausibility of a complaint, courts “accept factual allegations in the
15 complaint as true and construe the pleadings in the light most favorable to the nonmoving party.”
16 *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). Nonetheless,
17 Courts do not “accept as true allegations that are merely conclusory, unwarranted deductions of
18 fact, or unreasonable inferences.” *In re Gilead Scis. Secs. Litig.*, 536 F.3d 1049, 1055 (9th Cir.
19 2008).

20 Securities fraud cases have heightened pleading requirements as the complaint must satisfy
21 both the pleading requirements of Federal Rule of Civil Procedure 9(b) and the PSLRA. *In re*
22 *VeriFone Holdings, Inc. Sec. Litig.*, 704 F.3d 694, 701 (9th Cir. 2012). Pursuant to Rule 9(b),
23 claims alleging fraud must “state with particularity the circumstances constituting fraud...” Fed.
24 R. Civ. P. 9(b). The PSLRA mandates that “the complaint shall specify each statement alleged to
25 have been misleading, [and] the reason or reasons why the statement is misleading. . . [.]” 15
26 U.S.C. § 78u-4(b)(1)(B). The PSLRA further requires that the complaint “state with particularity
27 facts giving rise to a strong inference that the defendant acted with the required state of
28 mind.” *Tellabs, Inc. v. Makor Issues & Rts.*, 551 U.S. 308, 314 (2007) (quoting

1 15 U.S.C. § 78u-4(b)(2)(A)). This means a plaintiff must allege that “the defendant[] made false
2 or misleading statements either intentionally or with deliberate recklessness.” *In re VeriFone*
3 *Holdings*, 704 F.3d at 701 (quoting *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991
4 (9th Cir. 2009)).

5 Section 10(b) of the Securities Exchange Act makes it unlawful for any person to “use or
6 employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive
7 device or contrivance in contravention of such rules and regulations as the Commission may
8 prescribe as necessary or appropriate in the public interest or for the protection of
9 investors.” 15 U.S.C. § 78j(b). SEC Rule 10b-5 implements this provision, making it unlawful to,
10 among other things, “make any untrue statement of a material fact or to omit to state a material
11 fact necessary in order to make the statements made, in the light of the circumstances under which
12 they were made, not misleading[.]” 17 CFR § 240.10b-5(b).

13 III. DISCUSSION

14 A. Request for Judicial Notice

15 While the scope of review on a motion to dismiss is generally limited to the contents of the
16 complaint, courts may take judicial notice of facts that are “not subject to reasonable dispute.”
17 Fed. R. Evid. 201(b). Courts may consider documents incorporated into the complaint by
18 reference, *Tellabs*, 551 U.S. at 322, and take judicial notice of documents on which complaints
19 necessarily rely, *Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001), publicly available
20 financial documents such as SEC filings, *Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d
21 1049, 1064 n.7 (9th Cir. 2008), and publicly available articles or other news releases of which the
22 market was aware, *Heliotrope Gen., Inc. v. Ford Motor Co.*, 189 F.3d 971, 981 n.18 (9th Cir.
23 1999). The Court may not assume the truth of an incorporated document “if such assumptions
24 only serve to dispute facts in a well-pleaded complaint.” *Khoja v. Orexigen Therapeutics, Inc.*,
25 899 F.3d 988, 1003 (9th Cir. 2018).

26 Defendants seek judicial notice of 27 exhibits. They argue that 23 exhibits including press
27 releases, SEC filings, conference call and investor presentation transcripts, and documents issued
28 to the FDA, are incorporated by reference in the FAC as they are “extensively referenced in the

1 Complaint or otherwise form the basis of Plaintiff's claims." RJD (ECF 66) at 7. Plaintiffs agree
2 that Exhibits 2-17, 20, and 22-26 (press releases, earnings call and presentation transcripts, and
3 SEC) are incorporated by reference, but may not be considered for their truth. ECF 69 at 15.
4 Accordingly, the Court takes judicial notice of the incorporated documents but does not assume
5 the truth of disputed facts. *See Khoja*, 899 F.3d at 1003.²

6 Exhibit 19, a publicly available FDA guidance document, is also the proper subject of
7 judicial notice. "[C]ourts routinely take judicial notice of [] FDA guidance documents, many of
8 which also appear on the FDA's public website." *Immanuel Lake v. Zogenix, Inc.*, No. 19-CV-
9 01975-RS, 2020 WL 3820424, at *5 (N.D. Cal. Jan. 27, 2020) ("Zogenix") (citation omitted).
10 Because the document is accessible on the FDA's website (specifically, at
11 <https://www.fda.gov/media/109615/download>) as of the date of this order, its "accuracy cannot
12 reasonably be questioned," making it subject to judicial notice. Fed. R. Evid. 201(b).

13 Plaintiffs object to the Court taking judicial notice of Exhibits 1 (Review of Post-
14 Inspection Responses), 18 (Revance's Form 8-K filed with the SEC on May 26, 2021), and 27
15 (September 8, 2022 press release). ECF 69 at 17-19. Exhibits 1 and 18 are each referred to once
16 in the FAC, in passing reference, and do not form the basis of Plaintiffs' claims. *See* FAC ¶¶ 69,
17 109. Plaintiffs cite Exhibit 27 once in their FAC to discuss that the FDA approved Revance's
18 BLA for DAXI in September 2022, FAC ¶ 179, but argue that the eventual approval is not
19 relevant to their claims. Because these exhibits do not form the basis of Plaintiffs' claims, the
20 Court does not take judicial notice of Exhibits 1, 18, or 27.

21 Defendants argue that Revance's unredacted Form 483 Response, Ex. 21, is incorporated
22 by reference, as Plaintiffs attach the redacted version of the same document to the FAC (*see* ECF
23 58-3), and the document forms the basis of Plaintiffs' complaint. ECF 66 at 9. Plaintiffs do not
24

25 ² For example, the Court takes judicial notice of the fact that the documents, such as the press
26 releases, contained purportedly cautionary language about forward-looking statements. *See*
27 *Diversified Capital Invs., Inc. v. Sprint Commc'n, Inc.*, 2016 WL 2988864, at *4 (N.D. Cal. May
24, 2016) (taking "judicial notice of the existence and facial content of the press release," but not
for its truth); *In re Twitter, Inc. Sec. Litig.*, 2020 WL 4187915, at *3 (N.D. Cal. Apr. 17, 2020)
("the court will take judicial notice of the analyst reports, news articles, and SEC filings cited by
[p]laintiffs, but not for the truth of the matters asserted therein.").

1 dispute the accuracy or authenticity of the unredacted Form 483 Response but argue that it is not
2 incorporated by reference as it is not referred to extensively and does not form the basis of
3 Plaintiffs' claims. The Court agrees. Plaintiffs refer to the Form 483 Response on three occasions
4 in the FAC. *See* FAC ¶ 15 (explaining that Revance was able to address "minor deficiencies the
5 FDA identified" but could not address the ineffectiveness of the WCB and "incorrectly claim[ed]
6 that it was using 'the exact same process as proposed'"); ¶ 84 (Revance initiated a quality
7 investigation in September 2020 that determined in December 2020 that the root cause of the issue
8 was the effectiveness of the previously qualified WCB); *see also* FAC ¶ 110. However,
9 Revance's Form 483 Response does not form the basis of Plaintiffs' claims as the document
10 "creates a defense to the" FAC's allegations and Plaintiffs did not have access to the unredacted
11 document. *See Khoja*, 899 F.3d at 1001-02. Accordingly, the Court finds that Ex. 21 is not
12 incorporated by reference.

13 **B. Motion to Dismiss**

14 Defendants move to dismiss the FAC, arguing that the challenged statements are not
15 actionable because they are forward-looking statements protected by the PSLRA safe harbor or are
16 corporate puffery or opinion statements. Defendants further assert that any remaining statements
17 are not false or misleading or were made without scienter. The Court considers each argument in
18 turn.

19 **1. Forward-Looking Statements**

20 Under the PSLRA's "safe harbor" rule, a person is not liable for a false or misleading
21 "forward-looking statement" if 1) it is "accompanied by meaningful cautionary statements
22 identifying important factors that could cause actual results to differ materially" or 2) the forward-
23 looking statement is "immaterial" or 3) the plaintiff fails to prove it is made by a natural person
24 with "actual knowledge . . . that the statement was false or misleading." 15 U.S.C. § 78u-5(c); *see*
25 *Weston Fam. P'ship LLLP v. Twitter, Inc.*, 29 F.4th 611, 620 (9th Cir. 2022). A forward-looking
26 statement is "any statement regarding (1) financial projections, (2) plans and objectives of
27 management for future operations, (3) future economic performance, or (4) the assumptions
28 'underlying or related to' any of these issues." *No. 84 Emp.-Teamster Joint Council Pension Tr.*

1 *Fund v. Am. W. Holding Corp.*, 320 F.3d 920, 936 (9th Cir. 2003) (citing 15 U.S.C. § 78u-5(i)).

2 Defendants argue that these statements expressing anticipation of future FDA approval are
3 forward-looking statements protected by the PSLRA safe harbor:

- 4 • “Revance anticipates potential product approval in the second half of 2020.” FAC ¶ 115
5 (Nov. 25, 2019 Press Release).
- 6 • “Revance anticipates acceptance of the submission in the first quarter and projects
7 potential approval in the fourth quarter of 2020.” FAC ¶¶ 116 (January 9, 2020 Press
Release), 118 (Feb. 6, 2020 Press Release).
- 8 • “We continue to anticipate approval this year and, as we have noted before, the FDA did
9 not indicate that there were any other review issues beyond the pending inspection.”
FAC ¶ 143 (May 10, 2021 Press Release).
- 10 • “Revance continues to anticipate receiving approval for [DAXI] in 2021 and is actively
11 building inventory and preparing for commercial launch.” FAC ¶ 150 (Aug. 5, 2021 Press
Release), ¶ 155 (Aug. 5 2021 Earnings Call).
- 12 • “[T]he company continues to anticipate FDA approval of [DAXI] . . . in 2021.”
FAC ¶ 165 (Oct. 12, 2021 Press Release).

15 Plaintiffs do not dispute that these statements about the likelihood of FDA approval are forward-
16 looking. Opposition (ECF 68) at 24-24; *see Kovtun v. VIVUS, Inc.*, No. C 10-4957 PJH, 2012 WL
17 4477647, at *12 (N.D. Cal. Sept. 27, 2012) (“VIVUS”), *aff’d sub nom. Ingram v. VIVUS, Inc.*, 591
18 F. App’x 592 (9th Cir. 2015) (“Projections about the likelihood of FDA approval are forward-
19 looking statements. They are assumptions related to the company’s plan for its product, and as
20 such fall under the PSLRA’s safe harbor rule.”). Instead, Plaintiffs argue that the statements were
21 not accompanied by meaningfully cautionary language or were made with actual knowledge of
22 their falsity. Opposition at 24-25.

23 Statements that Defendants made prior to the July 2021 FDA inspection were accompanied
24 by cautionary language. Defendants repeatedly warned investors that forward-looking statements
25 are “subject to risks and uncertainties that could cause actual results to differ materially from our
26 expectations,” Ex. 3 (ECF 65-4) (Jan. 9, 2020 Press Release) at 3, Ex. 4 (ECF 65-5) (Feb. 6, 2020
27 Press Release) at 2, such as the “ability to obtain and maintain regulatory approval of our drug
28 product candidates,” Ex. 2 (ECF 65-3) (Nov. 25, 2019 Press Release) at 1, Ex. 3, Ex. 4, and the

1 “results, timing . . . and development activities and regulatory approvals, including the continuing
2 delay in the FDA’s approval of the BLA for [DAXI], including as a result of delays in the site
3 inspection conducted of our manufacturing facility . . . [and] observations made by the FDA
4 during the site inspection . . . due to COVID-19 . . . observations made by the FDA during the site
5 inspection and other reasons. . . [.]” Ex. 16 (ECF 65-17) (May 10 2021 Press Release) at 4, Ex. 22
6 (ECF 65-22) (Aug. 5, 2021 Press Release) at 4 (same).

7 Plaintiffs acknowledge that they “are not [] alleging that [Defendants] filed a BLA they
8 knew could never be approved.” Opposition at 10. Instead, they argue that the cautionary
9 statements were “boilerplate” as they fail to mention the actual risks facing BLA approval, such as
10 the ineffective WCB, the possibility of a CRL, and the issuance of the Form 483. *Id.* at 24-25.
11 However, Plaintiffs have not shown that prior to the issuance of the Form 483, and prior to
12 Revance determining the root cause of the rejected lots, Defendants believed or had reason to
13 believe that their projections of the timeline for BLA approval were inaccurate. Indeed, courts
14 have found less detailed cautionary statements to sufficiently caution investors. *See, e.g., Police*
15 *Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1059-60 (9th Cir. 2014) (“*Intuitive*
16 *Surgical*”) (“Actual results may differ materially from those expressed or implied, as a result of
17 certain risks and uncertainties. These risks and uncertainties are described in detail in the
18 company’s [SEC] filings. Prospective investors are cautioned not to place undue reliance on such
19 forward-looking statements.”); *In re Cutera Sec. Litig.*, 610 F.3d 1103, 1112 (9th Cir. 2010)
20 (“[T]hese prepared remarks contain forward-looking statements concerning future financial
21 performance and guidance . . . management may make additional forward-looking statements in
22 response to questions, and . . . factors like Cutera’s ability to continue increasing sales
23 performance worldwide could cause variance in the results.”). Thus, the pre-inspection statements
24 anticipating approval within a projected timeline are immunized. *See* FAC ¶¶ 115, 116, 143.

25 Plaintiffs also challenge the cautionary language as insufficient once Defendants received
26 the Form 483. For example, on August 5, 2021, Revance issued a press release stating that it
27 anticipated FDA approval in 2021. FAC ¶ 150. The press release included a warning that
28 forward-looking statements involved risks such as “the continuing delay in the FDA’s approval of

1 the BLA for [DAXI] . . . , including as a result of observations made by the FDA during the site
2 inspection . . . [.]” Ex. 22 at 4. Although the press release warns of the risk of delay due to FDA
3 observations, Plaintiffs argue that it does not caution investors of the risks that were already
4 realized – the rejected drug substance lots, that WCB qualification was not projected to be
5 complete until December 31, 2021, and the FDA had informed the company that its manufacturing
6 changes were inconsistent with the submitted BLA. FAC ¶¶ 86-87 (citing Ex. B at 22), 193.
7 Determining whether this language is meaningfully cautionary is a closer call. Cf. *In re Solarcity*
8 *Corp. Sec. Litig.*, 274 F. Supp. 3d 972, 993 (N.D. Cal. 2017) (warning language was meaningful
9 where it “specifically refers to a potential lack of demand and the potential that signed contracts
10 would be cancelled, the two risk factors that Plaintiffs allege that Defendants failed to disclose”).

11 Nonetheless, even if the language was not meaningfully cautionary, the statements are
12 protected under the safe harbor as Plaintiffs have failed to allege “with particularity facts giving
13 rise to a strong inference that the defendant acted with the required state of mind,” that is, “actual
14 knowledge . . . that the statement was false or misleading.” 15 U.S.C. § 78u-4(b)(2); 15 U.S.C. §
15 78u-5(c)(1)(B)(i); see *In re Cutera*, 610 F.3d at 1113. Plaintiffs argue that Defendants knew that
16 the ineffective WCB and Form 483 decreased the likelihood of BLA approval. Opposition at 25.
17 Although in hindsight, the projections may have been overly optimistic, Plaintiffs have not alleged
18 that Defendants knew that the projected timeline for BLA approval was not possible. See, e.g., *In*
19 *re Connetics Corp. Sec. Litig.*, 542 F. Supp. 2d 996, 1008 (N.D. Cal. 2008) (statements predicting
20 that the “FDA would approve [the drug] were not made in the face of actual knowledge that [the
21 drug] could never be approved; rather, they may have been made in the optimistic belief that the
22 transgenic testing problem was a surmountable barrier to FDA approval”). Defendants may have
23 reasonably believed that they could fix any deficiencies by the timeline they predicted. See *In re*
24 *Syntex Corp. Sec. Litig.*, 95 F.3d 922, 930 (9th Cir. 1996) (“Syntex was forecasting a future event.
25 Any alleged deficiencies in the testing procedures do not indicate that Syntex’s prediction of an
26 FDA approval date was false when made. Instead, the company could have known of problems in
27 the testing procedures, planned to remedy those deficiencies, and still thought it would achieve
28 FDA approval by the estimated date.”). Indeed, Defendants’ Form 483 Response shows that they

1 informed the FDA that they considered (Plaintiffs argue wrongfully so) WCB qualification to be a
2 post-approval activity. Ex. C at 10-11. Thus, Plaintiffs have not shown actual falsity, and the
3 statements about the anticipated timeline for DAXI approval are protected under the PSLRA safe
4 harbor. Accordingly, the Court **DISMISSES** the Section 10(b) claim with respect to the
5 statements about the anticipated timeline for DAXI approval.

6 **2. Corporate Optimism and Opinion Statements**

7 Defendants also argue that Plaintiffs challenge vague statements of optimism and opinion
8 statements that are not actionable. In the Ninth Circuit, “vague, generalized assertions of
9 corporate optimism or statements of ‘mere puffing’ are not actionable material misrepresentations
10 under federal securities laws” because no reasonable investor would rely on such statements. *City*
11 *of Royal Oak Ret. Sys. v. Juniper Networks, Inc.*, 880 F. Supp. 2d 1045, 1063 (N.D. Cal. 2012)
12 (quoting *In re Impac Mortg. Holdings, Inc. Sec. litig.*, 554 F. Supp. 2d 1083, 1096) (citing *Glen*
13 *Holly Entm’t, Inc. v. Tektronix, Inc.*, 352 F.3d 367, 379 (9th Cir. 2003)); *see In re Cutera*, 610
14 F.3d at 1111 (“professional investors, and most amateur investors as well, know how to devalue
15 the optimism of corporate executives”) (citation omitted). This is because “[w]hen valuing
16 corporations, . . . investors do not rely on vague statements of optimism like ‘good,’ ‘well-
17 regarded,’ or other feel good monikers.” *In re Cutera*, 610 F.3d at 1111. However, even “general
18 statements of optimism, when taken in context,” may be misleading “when those statements
19 address specific aspects of a company’s operation that the speaker knows to be performing
20 poorly.” *In re Quality Sys., Inc. Sec. Litig.*, 865 F.3d 1130, 1143 (9th Cir. 2017) (citation
21 omitted).

22 Expressions of opinions – as opposed to statements of fact – are only actionable if they are
23 both subjectively and objectively false or misleading. *Rubke v. Capitol Bancorp Ltd*, 551 F.3d
24 1156, 1162 (9th Cir. 2009) (citing *Va. Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1094-96
25 (1991)). “To be misleading, a statement must be “capable of objective verification.’ ” *Retail*
26 *Wholesale & Dep’t Store Union Loc. 338 Ret. Fund v. Hewlett-Packard Co.*, 845 F.3d 1268, 1275
27 (9th Cir. 2017) (quoting *Or. Pub. Emps. Ret. Fund v. Apollo Grp. Inc.*, 774 F.3d 598, 606 (9th Cir.
28 2014)).

1 The parties agree that Plaintiffs challenge various opinion statements:

- 2 • “the BLA filing represents a monumental achievement . . . Revance enters a catalyst-rich
3 calendar year of significant clinical trial readouts and meaningful Company milestones.”
4 FAC ¶ 115 (Nov. 25, 2019 Press Release).
- 5 • “This progress has set us up for a transformational 2020, a year which we believe will be
6 characterized by excitement and execution.” FAC ¶ 121 (Q4 2019 Earnings Call)
- 7 • “This is a very exciting and pivotal year for Revance . . .” FAC ¶ 116 (Jan. 9, 2020 Press
8 Release).
- 9 • “The FDA’s acceptance of our BLA for our next-generation neuromodulator product,
10 DAXI, is a significant achievement for Revance and a crucial step forward . . .” FAC ¶ 118
11 (Feb. 6, 2020 Press Release)
- 12 • “. . . Revance has constructed an exceptional start to what we believe will be
13 transformational year for the company.” FAC ¶ 119 (Feb. 24, 2020 Press Release).
- 14 • “[S]hould the anticipated approval of DaxibotulinumtoxinA for Injection in glabellar lines
15 be delayed, we believe that Revance is in a strong position, both commercially and
16 financially, to weather any near-term change in timing. Just as importantly, we remain
17 confident in the overall strength of our BLA submission for [DAXI].” FAC ¶¶ 130 (Nov.
18 9, 2020 Press Release) 132 (Nov. 9, 2020 Q3 Earnings Call); *see also* FAC ¶ 136 (Jan. 7,
19 2021 Press Release).
- 20 • “. . . we continue to feel very good about the quality of the submission . . .” FAC ¶ 133
21 (Nov. 9, 2020 Q3 Earnings Call)
- 22 • “We feel very good in terms of our preparedness . . . and continue to build product in
23 preparation for launch.” FAC ¶ 146 (June 8, 2021 Goldman Sachs Conference).
- 24 • “In closing, we’re very proud of our performance in the first half of the year and anticipate
25 a strong finish in the second half with the potential approval of [DAXI] . . . we feel very
26 good about our prep and where we were in that process and we continue all of our
27 preparations in the hopeful approval of the product.” FAC ¶¶ 155, 157 (Aug. 5, 2021 Q2
28 2021 Earnings Call).
- 29 • “But we feel really good about where we are in that process [for approval of the
30 neuromodulator].” FAC ¶ 159 (Sept. 9, 2021 Wells Fargo Conference).

31 Here, the Court finds that statements in FAC ¶¶ 115, 116, 118, 119, and 121 are statements
32 of corporate optimism. *See* FAC ¶ 115 (filing the BLA was a “monumental achievement”);
33 FAC ¶ 121 (the year will be full of “excitement and execution”); FAC ¶¶ 116, 119 (it is an
34

1 “exciting,” “pivotal,” and “transformational” year for Revance). These statements are “feel good
2 monikers” that are not actionable. *See In re Cutera*, 610 F.3d at 1111; *see also In re Solarcity*,
3 274 F. Supp. 3d at 994-95 (finding that the following statements were corporate puffery: “we’re
4 highly optimistic . . . about our growth,” “[d]emand remained as strong as ever,” “Q2 was an
5 amazing quarter,” and “I’m very happy with our continued ability to scale and [unbelievably]
6 strong sales”). Plaintiffs argue that these statements are objectively verifiable because Revance
7 was experiencing deficiencies that implicated readiness for BLA approval. Opposition at 23-24.
8 However, they cite no binding or persuasive caselaw in support of their contention that these
9 vague statements of optimism are actionable. For example, Plaintiffs do not explain how the
10 statement that the acceptance of the DAXI BLA is a “significant achievement” and a “crucial step
11 forward” is misleading to investors. *See* FAC ¶ 118. Such “mildly optimistic, subjective
12 assessment[s] . . . [do not] amount to a securities violation.” *See In re Cutera*, 610 F.3d at 1111;
13 *see, e.g., Bodri v. GoPro, Inc.*, 252 F. Supp. 3d 912, 924 (N.D. Cal. 2017) (statement that the
14 company was “enjoying terrific momentum” which was a “testament to the strength of the GoPro
15 brand” was corporate optimism even though plaintiffs alleged that sales were weak and within
16 days GoPro had cancelled orders). Accordingly, the statements in FAC ¶¶ 115, 116, 118, 119, and
17 121 are not actionable.

18 Next, Plaintiffs argue that pre-inspection statements about Revance’s “confidence” in the
19 BLA submission and the “good” feelings about preparedness for inspection were misleading as
20 Defendants knew they had not entered into a Quality Agreement (QA) or failed to disclose that the
21 opinions were formed “without a reasonable inquiry into the BLA’s completeness.” Opposition at
22 23. However, as discussed below, the failure to enter into the QA was not material as Defendants
23 were able to remedy it within days of the FDA’s observations. Ex. C at 12. Accordingly,
24 Plaintiffs have not shown that the pre-inspection statements that Revance felt “good” or
25 “confident” about the BLA submission and inspection (FAC ¶¶ 130, 132, 133, 136, 146) were
26 false when made.

27 Finally, Plaintiffs argue that statements made while aware of the rejected lots, the
28 ineffective WCB, and the Form 483 were misleading by omission. Opposition at 22-23. Even

1 assuming that Revance was not objectively ready for the FDA inspection because of the
2 ineffective WCB, Plaintiffs have not specifically pleaded that prior to the inspection Defendants
3 believed that their confidence in the BLA approval process or readiness for inspection was false.
4 Accordingly, statements in FAC ¶¶ 130, 132, and 133 that Defendants feel “good” and “confident”
5 about the approval process are not actionable. *See In re Siebel Sys., Inc. Sec. Litig.*, No. C 04-
6 0983 CRB, 2005 WL 3555718, at *4 (N.D. Cal. Dec. 28, 2005) (“That a new program has kinks
7 does not make a positive statement about the program false. If that were the case, the federal
8 securities laws would prevent software companies from making any positive statements about new
9 software”).

10 However, during the inspection, the FDA inspector explained that Revance’s assumption
11 that the manufacturing changes it made were “consistent with the BLA” was “incorrect.”
12 FAC ¶ 193. The Court agrees that at this point, statements that Revance felt good about its
13 preparedness for approval (FAC ¶¶ 155, 157, 159) were misleading given the FDA inspector’s
14 explanation. Indeed, after July 2, 2021, even if Defendants “genuinely believed” they were ready
15 for approval, Revance was “aware of undisclosed facts tending seriously to undermine the
16 statement’s accuracy.” *See City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align
Tech., Inc.*, 856 F.3d 605, 616 (9th Cir. 2017) (citations omitted). At this stage, the Court cannot
17 “conclude that the statement[s] [are] ‘so obviously unimportant to a reasonable investor that
18 reasonable minds could not differ on the question of their unimportance.’ ” *In re Energy Recovery
Inc. Sec. Litig.*, No. 15-CV-00265-EMC, 2016 WL 324150, at *20 (N.D. Cal. Jan. 27, 2016)
19 (citation omitted). Thus, statements in FAC ¶¶ 155, 157, and 159 may be actionable if Plaintiffs
20 have alleged scienter.

21 **3. Materially False or Misleading**

22 For a statement to be actionable under the PSLRA it must be false or misleading as well as
23 material. “Under Rule 10b-5, . . . a fraudulent omission is a failure to ‘state a material fact
24 necessary in order to make the statements made, in the light of the circumstances under which they
25 were made, not misleading.’ ” *Wochos v. Tesla, Inc.*, 985 F.3d 1180, 1188 (9th Cir.
26 2021) (quoting 17 C.F.R. § 240.10b-5(b)). A statement is misleading “if it would give a
27 28

reasonable investor the ‘impression of a state of affairs that differs in a material way from the one that actually exists.’” *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 985 (9th Cir. 2008) (quoting *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002)).

An omitted fact is material if there is a “substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the ‘total mix’ of information made available.” *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976). “The inquiry into materiality is ‘fact-specific.’ ” *In re Alphabet, Inc. Sec. Litig.*, 1 F. 4th 687, 700 (9th Cir. 2021) (quoting *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 43 (2011)). As such, “resolving materiality as a matter of law is generally appropriate ‘only if the adequacy of the disclosure or the materiality of the statement is so obvious that reasonable minds could not differ.’ ” *Id.* (citation omitted).

Plaintiffs challenge 29 statements as false and misleading prior to and after the FDA inspection. Defendants argue that Plaintiffs have not adequately alleged the falsity of any specific statement or shown that any statement is misleading and have not alleged that two Defendants made any statements. Defendants distinguish between statements made before the drug substance lots were rejected (August and September 2020), before the FDA inspection and issuance of the Form 483 (July 2021), and after the inspection. The Court considers the arguments below.

a. Pre-Inspection Statements (November 2019 Through August 2020)

Defendants made pre-inspection statements that Revance was “ready” for the FDA inspection and “feel[s] very good about the quality of the submission,” FAC ¶ 133, and the FDA “did not indicate there are any other review issues at this time, beyond the on-site inspection,” FAC ¶ 135. Plaintiffs argue that these statements are false or misleading given the quality control deficiencies³ – mainly, the lack of a Quality Agreement (“QA”) with a third-party facility, FAC ¶¶ 117, 120, 122, 125, 127, 129. Defendants argue that Plaintiffs have not alleged that any quality control deficiencies, if they did exist, were material, or that they needed to be disclosed.

³ Plaintiffs admit that the Form 483 Observations 4 and 5 (yield calculations and written procedures) are “minor” deficiencies. Opposition at 16.

1 Motion at 20-22.

2 As part of the BLA approval process, Revance was required to enter into a QA with a
3 third-party testing facility. FAC ¶ 94. However, Plaintiffs do not allege that a QA was needed in
4 2019 or 2020, when these statements were made. Allegations that Revance had leased a testing
5 facility since 2015, FAC ¶ 194, are insufficient to show that a QA was required at the time
6 Revance made statements about readiness for inspection. Further, Plaintiffs only point to the July
7 2021 Form 483 to demonstrate that a QA was necessary for the BLA. There is a “general
8 principle” that “to be actionable, a statement or omission must have been misleading at the time it
9 was made; liability cannot be imposed on the basis of subsequent events.” *Reese v. BP*
10 *Exploration (Alaska) Inc.*, 643 F.3d 681, 693 (9th Cir. 2011) (internal quotations omitted). Thus,
11 Plaintiffs have not specifically alleged that the 2019 and 2020 readiness statements or projected
12 timelines for approval were false.

13 Even if a QA was necessary in 2019 or 2020, Plaintiffs have not alleged that the lack of a
14 QA materially decreased the likelihood that the BLA would be approved on Defendants’ projected
15 timeline. Materiality requires a “substantial likelihood that the disclosure of the omitted fact
16 would have been viewed by the reasonable investor as having significantly altered the ‘total mix’
17 of the information available.” *Matrixx Initiatives*, 563 U.S. at 38 (citation omitted). Plaintiffs do
18 not dispute that Revance entered a new QA before responding to the Form 483, or that the FDA
19 inspected the third-party facility and identified no issues. Ex. C at 12; FAC ¶ 15. Thus, Plaintiffs
20 have not shown that failure to disclose the lack of a QA made statements about being “ready” or
21 anticipating approval by the end of the year materially misleading.

22 **b. Pre-Inspection Statements (November 2020 Through June 2021)**

23 Plaintiffs challenge the following statements as false or misleading due to the rejected drug
24 substance lots and the ineffective WCB:

- 25 • “Though the company’s BLA is still under review, the FDA did not indicate any further
26 outstanding review issues beyond the pending on-site inspection. The company remains
27 confident in its BLA submission and continues to work proactively with the FDA on a
28 preapproval inspection as soon as possible in 2021.” FAC ¶ 136 (Jan. 27, 2021 Press
Release); *see also* FAC ¶¶ 133 (Nov. 9, 2020 Earnings Call), 135 (Nov. 25, 2020 Press
Release).

- 1 • “We have the ability to manufacture our own botulinum toxin bulk drug substance to
2 support our clinical trial programs and eventually, our commercial production.”
3 FAC ¶ 138 (Feb. 25, 2021 10-K).
- 4 • “We remain ready to support an on-site inspection as soon as the agency is able to visit our
5 facility. And we continue to build drug product inventory in anticipation of approval and
6 are eager to introduce this unique product into the aesthetics market.” FAC ¶ 144 (May
7 10, 2021 Earnings Call); *see also* FAC ¶ 143.
- 8 • “[Approval decision] will be the next update. Obviously if there was something that was
9 not favorable, we would certainly release that, but really the next update would be
10 approval.” FAC ¶ 146 (June 8, 2021 Goldman Sachs Conference).

11 Defendants argue that these statements were not misleading as Plaintiffs have not alleged
12 that the WCB needed to be qualified before obtaining FDA approval and the statements did not
13 trigger a need to disclose that the rejected drug substance lots. Motion at 22-24; *see* Ex. C at 10-
14 11.

15 While there is no “freestanding completeness requirement,” a statement is misleading by
16 omission if it “affirmatively create[s] an impression of a state of affairs that differs in a material
17 way from the one that actually exists.” *Brody*, 280 F.3d at 1006. As recognized by the Supreme
18 Court, “whether an omission makes an expression of opinion misleading always depends on
19 context.” *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175,
20 190 (2015). Here, the context was that the WCB produced two drug substance lots that were
21 rejected in August and September 2020, FAC ¶ 81, in September 2020, Revance conducted a
22 quality investigation, and in May 2021 recommended corrective action and preventative action to
23 manufacture and qualify a new WCB with a projected timeline of December 31, 2021 – six
24 months after the pre-approval inspection. FAC ¶ 191.

25 Prior to May 2021, Revance had not yet determined the WCB was ineffective or would not
26 be qualified until the end of 2021. Further, Revance’s Form 483 Response shows that the new
27 WCB “performs as expected” and “consistently met the specification,” suggesting that the
28 statement about the ability to manufacture drug substance was not misleading or false when made.
Ex. C at 9. *See, e.g., Browning v. Amyris, Inc.*, No. 13-CV-02209-WHO, 2014 WL 1285175, at

1 *10 (N.D. Cal. Mar. 24, 2014) (statements that the company had created a process with
2 “industrial-scale production” were not false or misleading even if the company missed its
3 production targets, and limited or failed test runs were not inconsistent with statements that the
4 company “expects to begin” production in May).

5 Plaintiffs argue that by stating it was “ready” for inspection, Revance conveyed the
6 impression “that there was nothing material left to do for the inspection to be successful.”
7 Opposition at 16. However, Plaintiffs have not alleged that the WCB needed to be qualified prior
8 to the inspection for Revance to be “ready” for inspection. *See* FAC ¶ 80 (stating only that FDA
9 regulatory guidance requires that a newly prepared WCB be appropriately qualified by
10 characterization and testing); *see, e.g.*, *Zogenix, Inc.*, 2020 WL 3820424, at *8 (finding no falsity
11 where plaintiffs “appear to assume that defendants knew, at the time of filing the [new drug
12 application], that the failure to reference [] toxicity studies made the application facially deficient
13 and created an ‘exceedingly high risk’ of rejection, but plaintiffs pleaded no specific allegations to
14 support this critical assumption”). Indeed, Revance’s Form 483 Response indicates that it had
15 manufactured a new WCB that was undergoing qualification and that drug substance lots made
16 with the “same process” were “manufactured successfully and met the acceptance criteria . . . [.]”
17 Ex. C at 5. The *Zogenix* court explained that “were plaintiffs’ version of falsity the law, a
18 pharmaceutical company could be sued for securities fraud each and every time it received a [new
19 drug application] rejection from the FDA[,] . . . [as] [p]otential plaintiffs could merely parrot any
20 deficiency identified by the FDA rejection letter and then claim the company concealed from the
21 market that it failed to include this ‘necessary’ piece of information in its application.” 2020 WL
22 3820424, at *9. Similarly, Plaintiffs cannot rely on the FDA’s statements in the Form 483 and the
23 fact that the FDA ultimately denied the BLA to argue that Defendants concealed important
24 information from investors. Thus, Plaintiffs’ readiness statements in FAC ¶¶ 143-44 are not
25 actionable. However, even if these statements were actionable, Plaintiffs have failed to allege
26 scienter, which the Court addresses in Section 4 below.

27 **c. Post-Inspection Statements**

28 The FDA issued the Form 483 on July 2, 2021. Plaintiffs challenge the following post-

1 inspection statements as misleading for failure to disclose the Form 483 and the changed
2 manufacturing process:

- 3 • “The FDA initiated their pre-approval inspection of our manufacturing facility in June, and
4 we continue to anticipate approval of [DAXI] for Injection for the treatment of glabellar
5 lines in 2021. We are actively preparing for the launch . . . [.]” FAC ¶ 150 (Aug. 5, 2021
Press Release); *see also* FAC ¶ 155.
- 6 • “[O]ur BLA may receive a Complete Response Letter or another response from the FDA
7 identifying deficiencies that must be addressed, rather than an approval.” FAC ¶ 152
(Aug. 5, 2021 Form 10-Q).
- 8 • “So we continue to feel very good that they’re following sort of through with the expected
9 inspection plan. I think you’re sensing consistency with our tone around the expected
10 approval before year-end. We’ve taken advantage of this time to keep up sort of our
11 readiness for the inspection and continue to advance our commercial preparation plans.”
FAC ¶ 156 (Aug. 5, 2021 Q2 2021 Earnings Call)
- 12 • “[W]e’re focused on an approval certainly before the end of 2021, and have full
13 preparation and build schedule going on in the interim . . . [inspection] is a standard piece
14 that needs to happen before approval. So the next communication you’ll hear from us is
15 kind of once we get the decision. But again, come back to the fact that we feel very good
about our prep and where we were in that process . . .” FAC ¶ 157 (Aug. 5, 2021 Q2 2021
Earnings Call).
- 16 • “[W]e feel really good about where we are in that [approval] process. The last thing that
17 had to be completed as part of our approval was the on-site inspection, which did happen at
the end of [Q2].” FAC ¶ 159 (Sept. 9, 2021 Wells Fargo Conference).
- 18 • “A typical inspection is 1 to 2 weeks of sort of on-site inspection activities. Ours was a
19 very typical inspection.” FAC ¶ 161 (Sept. 9, 2021 Wells Fargo Conference).
- 20 • “[T]he company continues to anticipate FDA approval of [DAXI] in 2021. Revance notes
21 that the issuance of a Form 483 following the conclusion of an onsite inspection is not
uncommon. A Form 483 lists observations made by FDA representatives during the
22 inspection of a facility. A Form 483 does not constitute a final agency determination.
Revance provided its response to the Form 483 in July 2021 following a preapproval
23 inspection and is currently awaiting the FDA’s decision on its BLA for [DAXI]. The
company remains confident in the quality of its BLA submission and continues to
24 anticipate FDA approval in 2021.” FAC ¶ 165 (Oct. 12, 2021 Press Release).

25
26 Defendants argue that these statements are not false or misleading because they do not
27 refer to the outcome of the FDA inspection or state that Revance had not received a Form 483.
28 Motion at 23-24. The Court agrees with Defendants that the statement that the inspection was

1 “typical” was not misleading. *See* FAC ¶ 161. Plaintiffs argue that the inspection was not
2 “typical” in light of the “severity of certain Deficiencies identified in the Form 483 . . . [.]”
3 Opposition at 20. However, this statement was made immediately after stating that “[a] typical
4 inspection is 1 to 2 weeks,” implying that the “typical” comment referred to the length of the
5 inspection. *See* FAC ¶ 161. Moreover, Plaintiffs have not alleged that Form 483s are uncommon,
6 or even that they necessarily result in a Complete Response Letter. Accordingly, this statement
7 was not misleading.

8 Plaintiffs also contend that Revance’s statement that it “may receive a Complete Response
9 Letter or another response from the FDA identifying deficiencies that must be addressed, rather
10 than approval,” “put the Form 483 itself ‘in play.’ ” Opposition at 18 (citing FAC ¶ 152). The
11 Court agrees. Although Defendants were under no obligation to discuss the FDA process, once
12 they chose to discuss the process, they were required to do so in a way that was not misleading.
13 Stating that Revance “may” receive a response from the FDA identifying deficiencies was
14 misleading where Revance did not disclose that these risks “may already have come to fruition.”
15 *See Berson*, 527 F.3d at 987-90; *see also Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167,
16 1181 (9th Cir. 2009), *aff’d*, 563 U.S. 27 (2011) (misleading where the SEC Form spoke about the
17 risks of product liability claims in the abstract when the company was already being sued in a
18 product liability action). Moreover, at the inspection, the FDA assessor told Defendant Joshi
19 (Revance’s Chief Operating Officer and President of R&D and Products Operations) that the FDA
20 recommended that the BLA be withheld for lack of commercial readiness. FAC, Ex. B at 2.
21 Thus, at this point, it was misleading to tout Revance’s confidence in BLA approval, and
22 statements in FAC ¶¶ 150, 152, 155, 156, 157, 159, 165 may be actionable if Plaintiffs have
23 alleged scienter, which the Court explores in Section 4, below.

24 **d. Schilke and Joshi’s Liability**

25 Individuals are only liable for materially misleading or false statements that they “made.”
26 *Janus Cap. Grp., Inc. v. First Derivative Traders*, 564 U.S. 135, 141 (2011). A person or entity
27 who has “ultimate authority over the statement” is said to have made the statement. *Id.* at 142.
28 After *Janus*, courts have held that corporate officers who sign statements made with the SEC may

1 be said to have “made” the statement. *See Abdo v. Fitzsimmons*, No. 17-CV-00851-TSH, 2021
2 WL 616324, at *7 (N.D. Cal. Feb. 17, 2021); *Special Situations Fund III QP, L.P. v. Brar*, 2015
3 WL 1393539, at *3 (N.D. Cal. Mar. 26, 2015) (“Courts have consistently held that the signer of a
4 corporate filing is its ‘maker,’ because signing a filing implies ‘ultimate control’ over its
5 contents.”) (citation omitted) (citing cases).

6 Defendants argue that Defendants Schilke (Revance’s Chief Financial Officer) and Joshi
7 did not make any of the challenged statements, and thus are not liable. Motion at 19 n. 2.
8 Plaintiffs allege that Joshi effectively made several statements as he signed SEC filings that
9 contain false or misleading statements. Opposition at 21 (citing FAC ¶¶ 123-24, 138-39, 152-53).
10 Joshi may be held liable for false or misleading statements in SEC filings that he signed. *See*
11 *Abdo*, 2021 WL 616324, at *7.

12 Plaintiffs also argue that Schilke and Joshi effectively “made” statements because they
13 failed to correct false or misleading statements on conference calls that they attended. Motion at
14 21 (citing FAC ¶¶ 121-22, 126-29, 132-34, 144-45, 167). The Ninth Circuit has not determined
15 whether an officer may be liable for failing to correct false or misleading statements. Some courts
16 have held that a high-ranking officer may not “knowingly fail to correct” a false statement made
17 by another official. *McGuire v. Dendreon Corp.*, No. C07-800MJP, 2008 WL 5130042, at *8
18 (W.D. Wash. Dec. 5, 2008) (citation omitted) (citing cases). Other courts have held that an officer
19 is not liable for failure to correct another’s statements without factual allegations demonstrating
20 that the officer had “ultimate control and authority over those statements.” *See Hampton v. Aqua*
21 *Metals, Inc.*, No. 17-CV-07142-HSG, 2020 WL 6710096, at *17 (N.D. Cal. Nov. 16, 2020); *City*
22 *of Royal Oak*, 880 F. Supp. 2d at 1071 (Board Chairman not liable under *Janus* for statements that
23 other individual defendants made during investor calls). The Court finds persuasive the latter set
24 of cases as they comport with the Supreme Court’s requirement that “the maker of a statement is
25 the person or entity with ultimate authority over the statement . . . [.]” *Janus*, 564 U.S. at 142.
26 With the exception of the statements that Joshi signed, Plaintiffs have not alleged that Joshi had
27 ultimate authority over any of the statements pleaded, and Plaintiffs have not alleged that Schilke
28 had ultimate authority over any statements. Accordingly, Joshi and Schilke are not liable for

1 statements they did not correct. Plaintiffs may amend their pleadings to show that Joshi or Schilke
2 had ultimate authority over the oral statements made on investor calls.

3 **4. Scienter**

4 Defendants also challenge the sufficiency of Plaintiffs' allegations with respect to scienter.
5 Scienter is the intent to deceive, manipulate or defraud. *Tellabs*, 551 U.S. at 319. To establish
6 scienter, the complaint must "state with particularity facts giving rise to a strong inference that the
7 defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). The required state
8 of mind is "a mental state that not only covers 'intent to deceive, manipulate, or defraud,' but also
9 'deliberate recklessness.' " *Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 705 (9th Cir.
10 2016) (internal citations omitted). Deliberate recklessness is "'an *extreme* departure from the
11 standards of ordinary care,' which 'presents a danger of misleading buyers or sellers that is either
12 known to the defendant or is so *obvious* that the actor must have been aware of it.'" *In re
13 Alphabet, Inc. Sec. Litig.*, 1 F. 4th at 701 (emphasis in original) (quoting *Nguyen v. Endologix,
14 Inc.*, 962 F.3d 405, 414 (9th Cir. 2020)).

15 The "strong inference" required by the PSLRA "must be more than merely 'reasonable' or
16 'permissible'—it must be cogent and compelling, thus strong in light of other explanations."
17 *Tellabs*, 551 U.S. at 324. "Facts showing mere recklessness or a motive to commit fraud and
18 opportunity to do so provide some reasonable inference of intent, but are not sufficient to establish
19 a strong inference of deliberate recklessness." *In re VeriFone Holdings*, 704 F.3d at 701. "A
20 court must compare the malicious and innocent inferences cognizable from the facts pled in the
21 complaint, and only allow the complaint to survive a motion to dismiss if the malicious inference
22 is at least as compelling as any opposing innocent inference." *Zucco Partners*, 552 F.3d at 991
23 (9th Cir. 2009); *see Nguyen*, 962 F.3d at 415 (9th Cir. 2020). In evaluating whether a complaint
24 satisfies the "strong inference" requirement, courts must consider the allegations and other
25 relevant material "holistically," not "scrutinized in isolation." *In re VeriFone Holdings*, 704 F.3d
26 at 701-02 (citing *Tellabs*, 551 U.S. at 323, 326). Because scienter is a subjective inquiry, "the
27 ultimate question is whether the defendant knew his or her statements were false, or was
28 consciously reckless as to their truth or falsity." *Gebhart v. SEC*, 595 F.3d 1034, 1042 (9th Cir.

1 2010).

2 Plaintiffs rely on the following to support an inference of scienter: (1) Defendants'
3 knowledge of and access to the deficiencies and the Form 483; (2) the core operations doctrine;
4 and (3) Defendants' motives to artificially inflate its stock. Plaintiffs' scienter allegations fail for
5 several reasons.

6 Plaintiffs detail Defendant Joshi's access to information about the BLA and the FDA
7 approval process, FAC ¶¶ 183-187, and allege that Defendant Foley (Revance's Chief Executive
8 Officer) and Defendant Schilke also had access to this information because Joshi reports to Foley,
9 FAC ¶ 187, and these three Individual Defendants had weekly meetings, some of which related to
10 FDA inspection preparations, FAC ¶ 189. However, Plaintiffs cite to no authority showing that
11 simply reporting to another employee or having meetings about the general subject are sufficient
12 to show knowledge. Indeed, "[w]here a complaint relies on allegations that management had an
13 important role in the company but does not contain additional detailed allegations about the
14 defendants' actual exposure to information, it will usually fall short of the PSLRA standard." *S.*
15 *Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 784 (9th Cir. 2008) ("Killinger"). That is the case
16 here.

17 Further, knowledge of manufacturing issues alone is insufficient to show intent to deceive
18 or that Defendants were deliberately reckless. *See Connetics*, 542 F. Supp. 2d at 1008. With
19 respect to pre-inspection statements, Plaintiffs have not made any allegations that Defendants had
20 "contemporaneous knowledge" that a statement was false or misleading when made. *See VIVUS*,
21 2012 WL 4477647, at *19. Plaintiffs' theory is that Defendants knew of the existence of various
22 deficiencies, and therefore their statements about FDA approval were misleading. However,
23 Plaintiffs have not pointed to any allegations that Defendants believed that FDA approval was
24 unlikely or would be delayed because of the deficiencies.

25 Moreover, the Court must weigh plausible competing inferences. *Tellabs*, 551 U.S. at 323-
26 24. Plaintiffs contend that Defendants' awareness of the deficiencies shows scienter. Opposition
27 at 26-29. However, the problem is that Plaintiffs only allege that in hindsight, after receipt of the
28 Form 483, these deficiencies showed an intent to deceive. Even if Defendants' projections or

1 statements of confidence were overly optimistic, Plaintiffs have not alleged facts showing that
2 Defendants believed that the manufacturing issues could not be resolved quickly or that the FDA
3 would not approve the BLA.⁴

4 Plaintiffs argue that once Defendants knew that the WCB had deteriorated, that it would
5 not be qualified until the end of 2021, and the FDA issued the Form 483, there is a strong
6 inference of scienter. To sufficiently plead scienter for allegedly misleading omissions, however,
7 Plaintiffs must allege “a highly unreasonable omission” and facts to support the inference that
8 Defendants either knew that their omissions were misleading the investors or that the potential for
9 misleading the public was so obvious that Defendants must have been aware of it. *See Zucco
10 Partners*, 552 F.3d at 991. None of the facts alleged in the FAC relate to the Defendants’ state of
11 mind. Indeed, “even if a company knows that a problem exists, it could still honestly and in good
12 faith report that the company will continue to perform as expected. Management simply may have
13 been confident that they could overcome the problems or merely underestimated the severity of
14 such problems.” *Connetics*, 542 F. Supp. 2d at 1008 (quoting *In re CBT Group PLC Sec. Litig.*,
15 1999 WL 1249287 *3 (N.D. Cal. July 21, 1999)). As the pleadings show, Revance was in the
16 process of qualifying a new WCB and had already successfully produced drug substance lots with
17 the new WCB. Thus, there are no indications that Defendants intended to deceive investors by
18 stating their readiness for BLA inspection or FDA approval. In *Zogenix*, the court found
19 insufficient allegations of scienter as “Plaintiffs have no answer to defendants’ benign
20 explanation—namely that ‘Zogenix had every incentive to get it right the first time, and to put
21 FINTEPLA on the path to [FDA] approval,’ did not consciously engage in any ‘reckless gamble,’
22 but rather misread what the FDA was looking for in the FINTEPLA NDA.” 2020 WL 3820424, at
23 *11. The same is true here. Although Plaintiffs argue that Defendants knew or recklessly
24 disregarded information that “materially decreased the likelihood that the BLA would be approved
25 as submitted,” Opposition at 29, the FAC does not allege an intent to deceive, manipulate, or

26
27 ⁴ Plaintiffs also argue that Defendants were aware of the lack of the QA. Opposition at 27.
28 However, as discussed above in Section 3(a), the fact that the QA was quickly resolved after the
Form 483 observation suggests that failure to disclose the lack of a QA was not material.

1 defraud investors. Indeed, the Form 483 is not a final determination by the FDA, and although
2 evidently Revance's Form 483 Response did not satisfactorily address the FDA's concerns,
3 Defendants' misreading of what the FDA required does not show conscious intent to deceive or an
4 "extreme departure from the standards of ordinary care." *See In re Alphabet, Inc. Sec. Litig.*, 1 F.
5 4th at 701; *Zogenix*, 2020 WL 3820424, at *11.

6 Further, the statements that Plaintiffs cite – projections for the timeline for approval,
7 confidence in the BLA submission, and readiness for inspection – were not "so dramatically false"
8 that at least some corporate official must have known of their falsity upon publication. *See In re*
9 *NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1063-64 (9th Cir. 2014) (awareness of serious defects in
10 two important products was not enough to trigger corporate scienter). The more compelling
11 inference is that Revance believed it was on the path to approval, even after the issuance of the
12 Form 483, which is supported by the fact that the FDA approved the BLA the following year.
13 FAC ¶ 23. Accordingly, Plaintiffs have not pleaded scienter based on Defendants' purported
14 knowledge of manufacturing issues.

15 Plaintiffs' core operation allegations are also deficient. The "core operations" doctrine
16 allows the knowledge of certain facts that are critical to a business's "core operations" to be
17 attributed to a company's key officers. *Webb v. Solarcity Corp.*, 884 F.3d 844, 854 (9th Cir.
18 2018). "Allegations that rely on the core-operations inference are among the allegations that may
19 be considered in the complete PSLRA analysis." *Killinger*, 542 F.3d at 784. "[C]orporate
20 management's general awareness of the day-to-day workings of the company's business does not
21 establish scienter—at least absent some additional allegation of specific information conveyed to
22 management and related to the fraud." *Metzler*, 540 F.3d at 1068. Plaintiffs argue that it would be
23 "absurd to suggest" that Defendants were unaware of the deficiencies and the Form 483 while
24 making positive statements about the BLA and FDA inspection and approval timeline. Opposition
25 at 30. However, Plaintiffs have not made "detailed and specific allegations" supporting a strong
26 inference that Defendants Schilke or Foley were intimately involved in the minutiae of the BLA
27 process. *Zucco Partners*, 552 F.3d at 1000 (citation omitted). The fact that Defendants had
28 "some" meetings about the BLA and FDA approval process does not plausibly allege that specific

1 information was conveyed to Foley or Schilke. *See In re NVIDIA Corp.*, 768 F.3d at 1064. Even
2 assuming that knowledge could be imputed on the Individual Defendants under the core
3 operations doctrine, Plaintiffs again fail to show that knowledge of manufacturing deficiencies
4 meant that Defendants believed that the BLA was not ready or would not pass inspection, and thus
5 fail to show scienter under the core operations theory.

6 Plaintiffs also argue that Defendants had “compelling motives” to mislead investors to
7 keep stock prices inflated during the class period as their compensation came in the form of stock
8 and options. Opposition at 30-31 (citing FAC ¶¶ 212-13). But “evidence of a personal profit
9 motive on the part of officers and directors . . . is insufficient to raise a strong inference of
10 scienter.” *Intuitive Surgical*, 759 F.3d at 1064 (significant profits from sale of company stock did
11 not raise an inference of scienter); *see In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d 869, 884 (9th
12 Cir. 2012) (“allegations of routine corporate objectives such as the desire to obtain good financing
13 and expand are not, without more, sufficient to allege scienter”). Moreover, Plaintiffs fail to
14 acknowledge that the Ninth Circuit has “recognized that a lack of stock sales can detract from a
15 scienter finding.” *Webb*, 884 F.3d at 856. None of the Individual Defendants is alleged to have
16 sold Revance stock during the class period. *See In re Pixar Sec. Litig.*, 450 F. Supp. 2d 1096,
17 1107 (N.D. Cal. 2006) (“the absence of insider trading by a defendant is highly relevant and
18 undermines any inference of scienter”). In *Nguyen*, the Ninth Circuit found that the plaintiffs’
19 theory that defendants promised FDA approval that they knew would not be approved because of
20 migration problems “does not make a whole lot of sense,” and relies on the “supposition that
21 defendants would rather keep the stock price high for a time and then face the inevitable fallout”
22 when the migration problem was revealed. 962 F.3d at 415. However, there were no factual
23 allegations that the defendants sold any stock or sold the company at a premium during this time.
24 *Id.* Thus, the court found the allegations of fraud implausible. *Id.* The same is true here.
25 Therefore, the Court finds that Defendants’ general financial motives cannot show scienter. *See*
26 *id.* (“Treating the allegations in the complaint in the light most favorable to the plaintiff, the notion
27 that a company would promise FDA approval that it knew would not materialize does not, without
28 more, create a strong inference of intent to deceive or deliberate recklessness.”).

1 After having determined that none of Plaintiffs' allegations, standing alone, is sufficient to
2 create a strong inference of scienter, the Court now considers the allegations holistically. *See In re*
3 *VeriFone*, 704 F.3d at 702–03; *Zucco Partners*, 552 F.3d at 992. The Court finds that taken
4 together, the facts do not evince such fraudulent intent or deliberate recklessness as to make the
5 inference of scienter cogent. *See Tellabs*, 551 U.S. at 323-24. Indeed, as noted above, Plaintiffs'
6 factual allegations fail to sufficiently plead scienter as to any of the Defendants. Accordingly, the
7 Court **DISMISSES** the FAC with leave to amend.

8 **C. Section 20(a) Claim**

9 A Section 20(a) claim requires an underlying violation of securities law. *In re Rigel*
10 *Pharms.*, 697 F.3d at 886. Because Plaintiffs failed to adequately plead a violation under Rule
11 10b-5/Section 10(b), their Section 20(a) claim also fails. *See id.*

12 **IV. CONCLUSION**

13 For the foregoing reasons, the Court **GRANTS** Defendants' motion to dismiss with leave
14 to amend. Any amended complaint must be filed by **May 1, 2024**. No additional parties or claims
15 may be added without leave of Court or stipulation of Defendants.

17 **IT IS SO ORDERED.**

18 Dated: March 30, 2024

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23 **ARACELI MARTÍNEZ-OLGUÍN**
24 United States District Judge
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